Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1-5 have been amended, and claims 10-13, 18, 19, 22, and 23 have been canceled without prejudice. New claim 30 has been introduced, dependent upon claim 4. Claim 4 has been re-written in independent form. Claims 1-9, 14-17, 20, 21, and 24-30 remain pending, with claims 7-9, 14-17, 20, 21, and 24-29 being withdrawn. Claims 1-6 and 30 are under examination.

The objection to the sequences presented in Table 1 is acknowledged. The sequences are now presented according to customary use of the uppercase letters as L-amino acids and the lowercase letters as D-amino acids. The contrary usage in Table 1 of the application as originally filed stems from the fact that sequences PCP-8 through PCP-15 in Table 1 of WO 00/17348 used the same contrary usage. The statement in the paragraph preceding Table 1 of the present application (further amended herein) concerning the L- and D-amino acid symbols was intended only to apply to the sequences of Table 1, and not to other sequences identified in the present application. Thus, the presentation of sequences elsewhere in the present application were intended to abide by customary usage of uppercase letters as L-amino acids. Because PCP-8 through PCP-15 contain D-amino acids, these peptide sequences have not been listed in the previously submitted Sequence Listing. All other sequences in the application have been identified by sequence identifiers (SEQ ID NO: ##). The objection to the specification should therefore be withdrawn.

The rejection of claims 1-6 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is rendered moot by the above amendments. This rejection should therefore be withdrawn.

The rejection of claims 1-6 under 35 U.S.C. § 112 (second paragraph) is respectfully traversed in view of the above amendments. With respect to claim 5, the peptides originally recited therein are now presented in new claim 30. In new claim 30, the description of PCP-13.24 has been amended relative to original claim 5 such that the X residue is defined as D-cyclohexylalanine, which is consistent with the description in the specification at page 6, lines 13-20 (as amended). This amendment is consistent with the

description of this sequence in Table 1 of WO 00/17348, which is incorporated by reference in its entirety into the present application. In addition, the peptide name "PHG113" appears to be synonymous with "PCP-13" (D-amino acids ilghrdyk). Therefore, new claim 30 recites "PCP-13" but not "PHG113". In view of all of the foregoing and the accompanying claim amendments, withdrawal of the indefiniteness rejection is respectfully requested.

The rejection of claims 1-3 and 6 under 35 U.S.C. § 103(a) for obviousness over U.S. Patent No. 4,254,122 to Brown ("Brown") in view of any one of Farida et al., "Effects of Prostaglandin F_2alpha and its Synthesis Inhibitor Indomethacin on Corporaluteal Functions in Pseudopregnant Rats," *Bangladesh Medical Research Council Bulletin* 7(2):69-76 (1981) ("Farida"), Peplow et al., "Properties and Actions of Non-Steroidal Anti-Inflammatory Drugs, Including Their Effects on Prostaglandin and Macromolecular Biosynthesis," *Prostaglandins, Leukotrienes, and Essential Fatty Acids—Reviews* 33:239-252 (1988) ("Peplow"), and Robinson et al., "Regulation of Prostaglandin Synthesis by Antiinflammatory Drugs," *J. Rheumatology* 24(47):32-39 (1997) ("Robinson") is respectfully traversed.

Brown is cited for teaching that certain triazine compounds disclosed therein are effective inhibitors of prostaglandin synthetase, and further that other known inhibitors of prostaglandin synthetase (indomethacin or flufenamic) are clinically effective in the treatment of conditions such as menorrhagia.

Farida, Peplow, and Robinson are cited for identifying indomethacin as an inhibitor of prostaglandin biosynthesis generally, including $PGF_{2\alpha}$ synthesis.

The combination of Brown and any one or more of Farida, Peplow, and Robinson fails to identify which of the several prostaglandins is implicated in menorrhagia and whether agents that inhibit $PGF_{2\alpha}$–mediated signaling of the FP receptor would be expected to be useful in treating menorrhagia. Absent some teaching in the prior art that implicates $PGF_{2\alpha}$–mediated signaling of the FP receptor in menorrhagia, persons of skill in the art would not have been motivated to treat menorrhagia in the manner as presently claimed.

The non-obviousness of the present invention is further demonstrated by the failure of the literature to identify the presently claimed treatment for menorrhagia in the two decades since issuance of Brown and publication of Farida.

For these reasons, the rejection of claims 1-3 and 6 for obviousness over Brown in view of any one of Farida, Peplow, and Robinson is improper and should be withdrawn.

The rejection of claims 1-3 and 6 under 35 U.S.C. § 103(a) for obviousness over Tsang et al., "Endometrial Prostaglandins and Menorrhagia: Influence of a Prostaglandin Synthetase Inhibitor *in vivo*," *Can. J. Physiol. Pharmacol.* 65:2081-2084 (1986) ("Tsang") is respectfully traversed.

Tsang reports on elevated endometrial tissue levels of prostaglandin E ("PGE") and prostaglandin F ("PGF") associated with menorrhagia patients, and particularly the nearly three-fold higher levels of PGE over PGF. Tsang further reports that the cyclooxygenase inhibitor mefenamic reduces these prostaglandin levels in endometrial tissue as well as blood loss for menorrhagic patients. However, Tsang does not identify whether it is PGE or PGF that is responsible for the menorrhagia, and persons of skill in the art would not have expected agents that inhibit $PGF_{2\alpha}$ –mediated signaling of the FP receptor would be useful in treating menorrhagia.

As noted above, the non-obviousness of the present invention is further demonstrated by the failure of the literature to identify the presently claimed treatment for menorrhagia in the more than 15 years since publication of Tsang.

For these reasons, the rejection of claims 1-3 and 6 for obviousness over Tsang is improper and should be withdrawn.

Also accompanying this response is an information disclosure statement that has re-introduced the "foreign reference abstracts" stricken from the previously submitted information disclosure statement. The format recommended by the examiner on page 7 of the office action has been adopted. Because these references have already been submitted, duplicate copies of the references are not presented herewith. While applicants believe no fee is required for consideration of these references (as they were timely submitted), the PTO is nevertheless authorized to charge the $180 fee for their consideration to Deposit Acct. 14-1138 if it is determined by the examiner that the fee is required. If the PTO requires additional copies of these references, then applicants respectfully request that the examiner contact the undersigned attorney at the telephone number below.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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